

Notice of Allowability

Application No.

10/019,735

Applicant(s)

SASAKI ET AL.

Examiner

Art Unit

Rebecca E. Prouty

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 1/3/05.
2. ☒ The allowed claim(s) is/are 31-33 and 38.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 1/05
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lawrence Perry on 3/10/05.

EXAMINER'S AMENDMENT

Rewrite Claims 31 and 32 as follows:

31. (Currently Amended) A process for producing a sugar chain or complex carbohydrate, which comprises:

(A) selecting, as an enzyme source, a sugar chain synthesizing agent which comprises, as an active ingredient, a polypeptide consisting of (a) an amino acid sequence represented by SEQ ID NO:2, (b) an amino acid sequence of positions 45-372 in the amino acid sequence represented by SEQ ID NO:2, or (c) an amino acid sequence having 95% or more homology with the amino acid sequence in the above (a) or (b) and having β 1,3-N-acetylglucosaminyltransferase activity;

(B) allowing,

(1) the enzyme source,

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(2) an acceptor substrate selected from i) N-acetyllactosamine (Gal β 1-4GlcNAc), Gal β 1-3GlcNAc or lactose (Gal β 1-4Glc), ii) an oligosaccharide having an N-acetyllactosamine, Gal β 1-3GlcNAc or lactose structure at the non-reducing end, and iii) a complex carbohydrate having an N-acetyllactosamine, Gal β 1-3GlcNAc or lactose structure at the non-reducing terminal, and

(3) uridine-5'-diphosphate N-acetylglucosamine to be present in an aqueous medium to produce and accumulate a sugar chain or complex carbohydrate in which N-acetylglucosamine is added to a galactose residue of the acceptor substrate via a β 1-3-linkage; and

(C) recovering the sugar chain or complex carbohydrate from the aqueous medium.

32. (Currently Amended) The process for producing a sugar chain or complex carbohydrate of Claim 31, which further comprises:

(D) selecting, as an acceptor substrate, the N-acetylglucosamine-added reaction product obtained from step (C) of claim 31;

(E) allowing

(1) the acceptor substrate,

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(2) a GlcNAc β 1-4-galactosyltransferase, and

(3) uridine-5'-diphosphogalactose to be present in an aqueous medium to produce and accumulate a sugar chain or complex carbohydrate in which galactose is added to the N-acetylglucosamine residue at the non-reducing terminal of the acceptor substrate via a β 1-4-linkage; and

(E) recovering the galactose-added sugar chain or complex carbohydrate from the aqueous medium.

The following is an examiner's statement of reasons for allowance:

While the prior art (see for example WO 98/21328) teaches the protein of SEQ ID NO:2 and nucleic acids encoding this protein none of the prior art discloses that this protein has β 1,3-N-acetylglucosaminyltransferase activity. As such its use in methods for producing oligosaccharides and/or polylactosamine would not have been obvious to one of ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Rebecca Prouty", with a stylized, cursive script.

Rebecca Prouty
Primary Examiner
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